08/249,182

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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/249,182	05/25/94	STRACKE	M 20264149US1

EXAMINER	
LORING, S	

ART UNIT	PAPER NUMBER
1806	7

18M2/1129

PATENT BRANCH
OFFICE OF TECHNOLOGY TRANSFER
NATIONAL INSTITUTES OF HEALTH
BOX OTT
BETHESDA, MD 20892

DATE MAILED: 11/29/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☐ Responsive to communication filed on _____ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), 0 days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☒ Notice of Art Cited by Applicant, PTO-1449. (5 pages)
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 1-19 are pending in the application.
   Of the above, claims 1-8 and 10-19 are withdrawn from consideration.
2. ☐ Claims _____ have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claim 9 is ~~are~~ rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

PTOL-326 (Rev. 2/93)

15. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-2, 7-8 and 10-15, drawn to a DNA segment coding for a polypeptide comprising an amino acid sequence corresponding to autotaxin, a recombinant DNA molecule, a method of producing a recombinant autotaxin polypeptide and a method of purifying the autotaxin peptide, classified in Class 536, subclasses 23.1, 23.5; Class 435, subclasses 69.1, 69.7, and 91.4.

II. Claims 3-6 and 16-19, drawn to an isolated polypeptide comprising an amino acid sequence corresponding to autotaxin, classified in Class 530, subclass 350.

III. Claim 9, drawn to an antibody having binding affinity for autotaxin, classified in Class 530, subclass 388.21.

16. The inventions are distinct, each from the other because of the following reasons:

The products of groups I, II and III clearly differ in that they are structurally and functionally distinct and are made by different methods. The products of group I can be used for preparing recombinant probes. The product of group II can be used to produce triomas or to produce antibodies or can be used in immunopurification assays. The product of group III can be used to produce anti-idiotypic antibodies or in diagnostic immunoassays. Thus, the products clearly are independent and distinct from each other and additionally, differ in their classification scheme.

17. Because these inventions are distinct for the reasons given

above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification, restriction for examination purposes as indicated is proper.

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

19. During a telephone conversation with Dorothy Auth on August 17, 1994 a provisional election was made with traverse to prosecute the invention of group III, claim 9. Affirmation of this election must be made by applicant in responding to this Office action. Claims 1-8 and 10-19 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

20. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

21. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with

which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph as failing to provide an adequate written description of the claimed invention.

Applicant's attention is directed to Table 4 of the specification (page 29) and Example 4 (page 30). Peptide No. 10 found in Table 4 refers to the amino acid sequence DIEHLTSLDFFR as SEQ. ID. NO:10 having the name ATX 102, but Example 4 refers to the peptide, ATX-101, as SEQ. ID. NO:10. There exists an inconsistency within the specification as to the correct ATX number associated with SEQ. ID. NO:10. Correction is strongly suggested.

22. Claim 9 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

23. Claim 9 is rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to an antibody which specifically binds the motility stimulating protein, autotaxin, which has the amino acid sequence of SEQ. ID. NO. 10. The specification only provides a single example of producing an antibody to a specific amino acid sequence of autotaxin. The specification discloses that this "antibody has been used to perform immunohistochemical stains on human tissue." (page 30) The specification fails to enable the use of an antibody to any other specifically identified sequence disclosed in the specification. The specification additionally fails to enable the use of any

"binding fragment thereof" which would be functional for immunohistochemical staining as the Fab portion is responsible for binding specifically to a particular antigen, but the Fc portion is capable of interacting with different cells of the immune system or the complement system. One of ordinary skill in the art would have been able to produce an antibody to any of the specifically identified sequences disclosed in the specification, but the specification fails to enable the utility directed to any and all of the denoted sequences. The specification clearly states that "the protein of the present invention is unique from any previously identified or purified motility factor", in addition to there being a "need to predict the aggressiveness of a patient's individual tumor", but the specification has only provided evidence of making a single antibody which would provide a functional utility. Page 31-32 of the specification teach the use the peptide ATX-102 to produce antibodies useful for immunohistochemical techniques. Since the specification is inconsistent as to whether ATX-101 or ATX-102 is the correct name, the Examiner suggests that applicant determine whether or not the correct name of the peptide is used on page 31 of the specification. It is suggested that applicant amend the claim and/or specification or provide evidence in the form of a Declaration showing the production of additional antibodies which have a functional utility. See M.P.E.P. §§ 706.03(n) and 706.03(z).

24. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this

section made in this Office action:

> A person shall be entitled to a patent unless --
> (f) he did not himself invent the subject matter sought to be patented.

25. Claim 9 is rejected under 35 U.S.C. § 102(f) as being evidence of non-inventorship by Murata, J. et al.

Applicant is reminded that the date of publication is after the filing date of the instant application, but the rejection is based on the inventive entity not the publication date. The Murata et al. reference includes the authors Murata, Arestad, Liotta and Stracke. The reference teaches the production of anti-peptide antibodies to the ATX peptide, ATX-102. This is the same invention as claimed solely by Stracke, Liotta, Schiffmann, and Krutzsch in the instant application. The abstract teaches "(w)e have utilized affinity-purified anti-peptide antibodies to the ATX peptide, ATX-102, to screen an A2058 cDNA expression library made in λgt11. Positive clones were confirmed by antibody competition with specific peptides but not unrelated peptide. We obtained a partial cDNA clone of ATX which contains 1084 bases, including the poly-adenylation site and the AATAAA locus" thus, indicating more than Liotta and Stracke were involved in the claimed invention. The reference presents an ambiguity with regard to authorship because it is in the names of Murata, Arestad, Liotta and Stracke, only Liotta and Stracke are listed as inventors herein. The reference says nothing about inventorship. Because of this ambiguity, it is incumbent on applicants to provide a satisfactory showing which

would lead to a reasonable conclusion that applicant alone is the inventor of the claimed invention. In re Katz, 687 F.2d 450, 215 USPQ 14 (CCPA 1982). To resolve the ambiguity, applicants may file declarations by the non-applicant co-authors of the reference disclaiming the invention or a declaration by applicant setting forth the facts which provide an explanation as to why the non-applicant co-authors are not inventors. MPEP 715.01(c)

26. The oath or declaration is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by its Serial Number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The oath or declaration is defective because: under 120 priority, Serial No. 07/952,796 is disclosed. This application does not appear to have any connection with the instant application. Priority to Serial No. 08/822,043 has been disclosed in the first paragraph of Application Serial No. 08/249,182. Submission of a new oath properly claiming priority to Serial No. 07/822,043 is required.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Susan A. Loring whose telephone number is (703) 308-3998. The Examiner can normally be reached on Monday-Thursday from 6:30 AM-4:00 PM. The Examiner can also be reached on alternate Fridays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, David Lacey, can be

reached on (703)-308-3535. The fax phone number for this Group is (703)-305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Susan A. Loring
November 28, 1994

DAVID L. LACEY
SUPERVISORY PATENT EXAMINER
GROUP 180
11/29/94